



Attorney Docket No. T9005.A.1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: YOUNGRO BYUN et al.)
)
TITLE: ORAL DELIVERY OF)
MACROMOLECULES)
)
SERIAL NO.: 10/727,078) INFORMATION DISCLOSURE
) STATEMENT UNDER 37 C.F.R.
FILED: December 2, 2003) § 1.97
)
EXAMINER: _____)
)
ART UNIT: 1623)

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Please find, pursuant to 37 C.F.R. § 1.98(a)(1), the enclosed Form PTO-1449, which contains a list of patents, publications, or other items that have come to the attention of one or more of the individuals designated in 37 C.F.R. § 1.56(c). Applicant respectfully invokes the Patent Office's obligation under 37 C.F.R. § 1.97 to consider these references and make them of record in the above-captioned application. While no representation is made that any of these references may be "prior art" within the meaning of that term under 35 U.S.C. §§ 102 or 103, the enclosed list of

Certificate of Deposit Under 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the 2nd day of July, 2004.

Alan J. Howarth
Attorney Registration No. 36,553

references is disclosed so as to fully comply with the duty of disclosure set forth in 37 C.F.R. § 1.56.

Moreover, while no representation is made that a specific search of office files or patent office records has been conducted or that no better art exists, the undersigned attorney of record believes that the references listed, together with any other references which may have been previously cited by or submitted to the Office, are the closest to the claimed invention (taken in its entirety) of which the undersigned is presently aware, and no art which is closer to the claimed invention (taken in its entirety) has been knowingly withheld.

In accordance with 37 C.F.R. §§ 1.97 and 1.98, a copy of each listed reference (or relevant portion thereof) that was not previously submitted to, or cited by, the Patent Office is also enclosed.

Statement of References Previously Disclosed
Under 37 C.F.R. § 1.98(d)

The references listed on the enclosed Form PTO-1449 are not required to be provided under 37 C.F.R. § 1.98(d), and are therefore not enclosed, because they were previously cited by or submitted to the Office in application number 09/845,827 (now U.S. Patent No. 6,656,922), which is relied upon for an earlier filing date under 35 U.S.C. § 120.

Please charge any additional fees or credit any overpayment to
Deposit Account No. 50-0836.

DATED this 2nd day of July, 2004.

Respectfully submitted,



Alan J. Howarth
Attorney Registration No. 36,553

CLAYTON, HOWARTH & CANNON, P.C.
P.O. Box 1909
Sandy, UT 84091
Telephone: (801) 255-5335
Facsimile: (801) 255-5338

AJH/kdl

S:\CHC Files\T 9--\T90--\T9005\A\1\IDS.wpd



| | | |
|--|-------------------------------|-----------------------|
| PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE | ATTY. DOCKET NO. T9005.A.1 | SERIAL NO. 10/727,078 |
| | APPLICANT Youngro Byun et al. | |
| | FILING DATE December 2, 2003 | GROUP 1623 |

LIST OF PRIOR ART CITED BY APPLICANT

U.S. PATENT DOCUMENTS

| EXAMINER INITIALS | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|----------------------|----|--------------------|---------------|--------------------------|-------|----------|-------------------------------|
| | AA | 4,857,602 | Aug. 15, 1989 | Casey et al. | | | |
| | AB | 5,840,387 | Nov. 24, 1998 | Berlowitz-Tarrant et al. | | | |
| | AC | 5,855,618 | Jan. 5, 1999 | Patnaik et al. | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | |
|--|--|--------------------|------|---------|-------|----------|-------------|----|
| | | | | | | | YES | NO |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

OTHER PRIOR ART (Including Author, Title, Volume and/or Name of Publication, Relevant Pages and Date [as available])

| | | | |
|--|----|--|--|
| | AD | | R. Altman et al., Oral Anticoagulant Treatment with and without Aspirin, 74(1): F.K. Schattauer Verlagsgesellschaft mbH (Stuttgart) 556-510 (1995). |
| | AE | | D Brayden et al., Heparin Absorption across the Intestine: Effects of Sodium <i>n</i> -[8-(2-Hydroxybenzoyl) Amino] Carylrate in Rat <i>In Situ</i> Instillations and in Caco-2 Monolayers, 14 (12): Pharmaceutical Research 1772-1779 (1997). |
| | AF | | F. Diancourt et al., 11(3): Journal of Bioactive and Compatible Polymers 203-218 (July, 1996). |

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| | | | | | | | |
|---|--|--|--|-------------------------------|--|-----------------------|--|
| PTO-1449 | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY. DOCKET NO. T9005.A.1 | | SERIAL NO. 10/727,078 | |
| LIST OF PRIOR ART CITED BY APPLICANT | | | | APPLICANT Youngro Byun et al. | | | |
| | | | | FILING DATE December 2, 2003 | | GROUP 1623 | |

| U.S. PATENT DOCUMENTS | | | | | | | |
|-----------------------|--------------------|------|------|-------|----------|-------------------------------|--|
| EXAMINER INITIALS | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | | |
|--------------------------|------|---------|-------|----------|-----------------------|--|--|
| DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES NO | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| OTHER PRIOR ART (Including Author, Title, Volume and/or Name of Publication, Relevant Pages and Date [as available]) | | | |
|--|--|--|--|
| AG | | R. Hull et al., Hirudin versus heparin and low-molecular-weight heparin: And the winner is..., 132 J. Lab Clin Med 151-174 (1998). | |
| AH | | P. Klement et al., Hirudin causes more bleeding than heparin in a rabbit ear bleeding model, 132 J. Lab Clin Med 181-185 (1998). | |
| AI | | B. Koefoed et al., Effect of Fixed Minidose Warfarin, Conventional Dose Warfarin and Aspirin on INR and Prothrombin Fragment 1+2 in Patients with Atrial Fibrillation, 77(5) F.K. Schattauer Verlagsgesellschaft mbH (Stuttgart) 845-848 (1997). | |
| EXAMINER | | DATE CONSIDERED | |

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| | | | | | | | |
|--|----|--|--|-------------------------------|-------|-----------------------|-------------------------------|
| PTO-1449 | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY. DOCKET NO. T9005.A.1 | | SERIAL NO. 10/727,078 | |
| LIST OF PRIOR ART CITED BY APPLICANT | | | | APPLICANT Youngro Byun et al. | | | |
| | | | | FILING DATE December 2, 2003 | | GROUP 1623 | |
| U.S. PATENT DOCUMENTS | | | | | | | |
| EXAMINER INITIALS | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| FOREIGN PATENT DOCUMENTS | | | | | | | |
| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | <u>TRANSLATION</u> YES NO |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| OTHER PRIOR ART (Including Author, Title, Volume and/or Name of Publication, Relevant Pages and Date [as available]) | | | | | | | |
| | AJ | | Y.-K. Lee et al., Preparation of Slightly Hydrophobic Heparin Derivatives which Can Be Used for Solvent Casting in Polymeric Formulation, 92 Thrombosis Res. 149-156 (1998). | | | | |
| | AK | | Y.-K. Lee et al., Oral Delivery of New Heparin Derivatives in Rats, 17 Pharma. Res. 1259-1264 (2000). | | | | |
| | AL | | A. Leone-Bay et al., Oral Delivery of Sodium Cromolyn: Preliminary Studies In Vivo and In Vitro, 13(2) Pharmaceutical Research 222-226 (1995). | | | | |
| EXAMINER | | | | DATE CONSIDERED | | | |
| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | | | | | | |

| | | | | | | | |
|---|--|--|--|-------------------------------|--|-----------------------|--|
| PTO-1449 | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY. DOCKET NO. T9005.A.1 | | SERIAL NO. 10/727,078 | |
| LIST OF PRIOR ART CITED BY APPLICANT | | | | APPLICANT Youngro Byun et al. | | | |
| | | | | FILING DATE December 2, 2003 | | GROUP 1623 | |

| U.S. PATENT DOCUMENTS | | | | | | | |
|-----------------------|--|--------------------|------|------|-------|----------|-------------------------------|
| EXAMINER INITIALS | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | | |
|--------------------------|--|--------------------|------|---------|-------|----------|-----------------------|
| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES NO |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| OTHER PRIOR ART (Including Author, Title, Volume and/or Name of Publication, Relevant Pages and Date [as available]) | | | |
|--|----|--|---|
| | AM | | A. Leone-Bay et al., N-Acylated α -Amino Acids as Novel Oral Delivery Agents for Proteins, 38 J. Med. Chem. 4263-4269 (1995). |
| | AN | | A. Leone-Bay et al., Microsphere Formation in a Series of Derivatized α -Amino Acids: Properties, Molecular Modeling, and Oral Delivery of Salmon Calcitonin, 38 J. Med Chem 4257-4262 (1995). |
| | AO | | A. Leone-Bay et al., 4-[4-(2-Hydroxybenzoyl)amino]phenyl butyric Acid as a Novel Oral Delivery Agent for Recombinant Human Growth Hormone, 39 J. Med Chem. 2571-2578 (1996). |
| EXAMINER | | | DATE CONSIDERED |

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| | | | | | | | |
|---|--|--|--|-------------------------------|--|-----------------------|--|
| PTO-1449 | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY. DOCKET NO. T9005.A.1 | | SERIAL NO. 10/727,078 | |
| LIST OF PRIOR ART CITED BY APPLICANT | | | | APPLICANT Youngro Byun et al. | | | |
| | | | | FILING DATE December 2, 2003 | | GROUP 1623 | |

| U.S. PATENT DOCUMENTS | | | | | | | |
|-----------------------|--------------------|------|------|-------|----------|-------------------------------|--|
| EXAMINER INITIALS | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | | |
|--------------------------|------|---------|-------|----------|-----------------------|--|--|
| DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES NO | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| OTHER PRIOR ART (Including Author, Title, Volume and/or Name of Publication, Relevant Pages and Date [as available]) | | |
|--|--|---|
| AP | | A. Leone-Bay et al., The evolution of an oral heparin dosing solution, 22(8) Drugs of the Future 885-891 (1997). |
| AQ | | A. Leone-Bay et al., Acylated non- α -amino acids as novel agents for the oral delivery of heparin sodium, USP, 50 Journal of Controlled Release 41-49 (1998). |
| AR | | A. Leone-Bay et al., Synthesis and Evaluation of Compounds that Facilitate the Gastrointestinal Absorption of Heparin, 41 J. Med. Chem. 1163-1171 (1998). |

| | |
|-----------------|------------------------|
| EXAMINER | DATE CONSIDERED |
|-----------------|------------------------|

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| | | | | | | | |
|---|----|--|--|-------------------------------|-------|-----------------------|-------------------------------|
| PTO-1449 | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY. DOCKET NO. T9005.A.1 | | SERIAL NO. 10/727,078 | |
| LIST OF PRIOR ART CITED BY APPLICANT | | | | APPLICANT Youngro Byun et al. | | | |
| | | | | FILING DATE December 2, 2003 | | GROUP 1623 | |
| U.S. PATENT DOCUMENTS | | | | | | | |
| EXAMINER INITIALS | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| FOREIGN PATENT DOCUMENTS | | | | | | | |
| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES NO |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| OTHER PRIOR ART (Including Author, Title, Volume and/or Name of Publication, Relevant Pages and Date [as available]) | | | | | | | |
| | AS | | S. Milstein et al., Partially unfolded proteins efficiently penetrate cell membranes—implications for oral drug delivery, 53 Journal of Controlled Release 259-267 (1998). | | | | |
| | AT | | G.E. Raskob, Msc. Low molecular weight heparin, heparin, and warfarin, 2 Current Opinion in Hematology 372-379 (1995). | | | | |
| | AU | | G.J. Russell-Jones, Carrier-mediated Transport, Oral Drug Delivery, in 1 Controlled Drug Delivery 173-183 (E. Mathiowitz ed. 1999). | | | | |
| EXAMINER | | | | DATE CONSIDERED | | | |
| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | | | | | | |

| | | | | | | | |
|---|--|--|--|-------------------------------|--|-----------------------|--|
| PTO-1449 | | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY. DOCKET NO. T9005.A.1 | | SERIAL NO. 10/727,078 | |
| LIST OF PRIOR ART CITED BY APPLICANT | | | | APPLICANT Youngro Byun et al. | | | |
| | | | | FILING DATE December 2, 2003 | | GROUP 1623 | |

| U.S. PATENT DOCUMENTS | | | | | | | |
|-----------------------|--|--------------------|------|------|-------|----------|-------------------------------|
| EXAMINER INITIALS | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | | |
|--------------------------|--|--------------------|------|---------|-------|----------|-----------------------|
| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION YES NO |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

| OTHER PRIOR ART (Including Author, Title, Volume and/or Name of Publication, Relevant Pages and Date [as available]) | | | |
|--|----|--|--|
| | AV | | P.W. Swaan et al., Enhanced Transepithelial Transport of Peptides by Conjugation to Cholic Acid, 8 Bioconjugate Chem. 520-525 (1997). |
| | AW | | L. Wallentin, Unstable coronary artery disease—need for long term antithrombotic treatment, Aspirin alone is not sufficient, I would associate anticoagulant, 33 Cardiovascular Research 292-294 (1997). |
| | AX | | E. Windsor & G. Cronheim, Gastro-Intestinal Absorption of Heparin and Synthetic Heparinoids, 190 Nature 263-264 (1961). |
| EXAMINER | | | DATE CONSIDERED |

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.